

EXHIBIT B



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Premarket Approval (PMA)



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Note: This medical device record is a PMA supplement. A supplement may have changed the device description/function or indication from that approved in the original PMA. Be sure to look at the [original PMA](#)²³ record for more information.

Device	NUCLEUS CI522 COCHLEAR IMPLANT SYSTEM
Generic Name	Implant, Cochlear
Applicant	Cochlear Americas 13059 East Peakview Avenue Centennial, CO 80111
PMA Number	P970051
Supplement Number	S126
Date Received	11/14/2014
Decision Date	06/15/2015

Product Code [MCM](#)²⁴

Advisory Committee Ear Nose & Throat
Supplement Type Normal 180 Day Track
Supplement Reason Change
 Design/Components/Specifications/Material
Expedited Review Granted? No

Combination Product No

Approval Order Statement

APPROVAL FOR THE CI522 COCHLEAR IMPLANT.

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Page Last Updated: 09/14/2020

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